



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

1338 '99 MAY -7 P3:42

• MAY - 5 1999

Re: Tazorac®  
Docket No.: 98E-0474

The Honorable Q. Todd Dickinson  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,089,509, filed by Allergan, Inc., under 35 U.S.C. § 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for Tazorac®, the human drug product claimed by the patent.

The total length of the regulatory review period for Tazorac® is 2,684 days. Of this time, 1,958 days occurred during the testing phase and 726 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 8, 1990.

The applicant claims February 16, 1990, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 8, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 19, 1995.

FDA has verified the applicant's claim that the New Drug Application (NDA) for Tazorac® (NDA 20-600) was initially submitted on June 19, 1995.

3. The date the application was approved: June 13, 1997.

FDA has verified the applicant's claim that NDA 20-600 was approved on June 13, 1997.

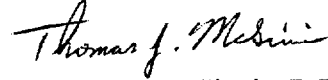
98E-0474

LET3/ANS

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "Thomas J. McGinnis".

Thomas J. McGinnis, R.Ph.  
Deputy Associate Commissioner  
for Health Affairs

cc: Robert J. Baran  
Allergan, Inc.  
2525 Dupont Drive  
Irvine, CA 92612

DATE: MAY - 5 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Tazorac®  
Docket No. 98E-0474, FRDTS# OC99126

Attached is a FR Notice for the human drug product, Tazorac®. This document has been internally reviewed and cleared by OHA.

Please note that Tazorac® is a registered trademark. Therefore, the superscript "R" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

7337 '99 MAY -7 P3:42

**Memorandum**

Date: **MAY - 5 1999**

From: Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application  
for Tazorac<sup>®</sup>

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0474** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,089,509**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98E-0474